

A phase III, multinational, randomised, double-blind, placebo-controlled, parallel-group study to investigate the clinical efficacy and safety of Diapep277™ in newly diagnosed type one diabetes patients

Submission date

28/09/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

21/10/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

13/06/2016

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00615264

Protocol serial number

901

Study information

Scientific Title

A phase III, multinational, randomised, double-blind, placebo-controlled, parallel-group study to investigate the clinical efficacy and safety of Diapep277™ in newly diagnosed type one diabetes patients

Acronym

DIA-AID

Study objectives

To test the hypothesis that pancreatic beta-cell function with DiaPep277™ is superior to that with placebo after 24 months.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type one diabetes

Interventions

1 mg DiaPep277™ or placebo will be administered subcutaneously at baseline (zero), one, three, six, nine, 12, 15, 18 and 21 months visits for a total of nine administrations.

Both treatment groups will be balanced for HbA1c values (HbA1c inferior to 7.0% and HbA1c superior or equal to 7.0%) and basal fasting C-peptide concentrations (C-peptide < 0.40 nmol/L and C-peptide ≥ 0.40 nmol/L). [Changed on 05/03/07 from ' Both treatment groups will be balanced for HbA1c values (stratum A: patients with HbA1c less than 7.0%, stratum B: patients with HbA1c equal to or more than 7.0%).'].]

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

DiaPep277™

Primary outcome(s)

Investigate the effect of DiaPep277™ versus placebo in patients with Type one Diabetes Mellitus on pancreatic beta-cell function as measured by stimulated C-peptide secretion after 24 months

Key secondary outcome(s)

1. Assess the effect of DiaPep277™ on insulin dose requirement after 24 months
2. Assess the effect of DiaPep277™ versus placebo on metabolic control as measured by % HbA1c after 24 months and by glucose profile during the study
3. Assess the safety and tolerability of DiaPep277™ during the study
4. Assess the effects of DiaPep277™ on the occurrence of hypo- and hyper-glycemic events during the study

Completion date

31/08/2010

Eligibility

Key inclusion criteria

At screening:

1. The patient has a diagnosis of type one diabetes mellitus according to the American Diabetes Association (ADA)/World Health Organisation (WHO) for up to 3 months (changed from 6 months on 05/03/2007)
2. Evidence of residual beta-cell function demonstrated by basal fasting C-peptide concentrations more than or equal to 0.22 nmol/l
3. Presence of one or more of the following criteria:
 - 3.1. At least one diabetes-related autoantibody: IA-2, insulin or glutamic acid decarboxylase (GAD) at screening and/or
 - 3.2. Age at diagnosis less than 20 years and ketonuria at diagnosis
4. The patient is on insulin treatment for diabetes since diagnosis
5. The patient is male or female, aged 16 to 45 years, inclusive
6. If a female of child-bearing potential, the patient is not pregnant or lactating, and will use oral hormonal contraception or other equally effective contraceptive methods throughout the study. The partners of male patients, who are of child-bearing potential, should also use adequate contraception in order to avoid pregnancies

Inclusion criteria removed on 05/03/2007: the patient has HbA1c of less than or equal to 9% within seven days prior to baseline visit

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. The patient is treated with inhaled insulin (changed from 'has an insulin pump in situ or is treated with inhaled insulin' on 05/03/07)
2. The patient has clinical evidence of any diabetes-related complication that in the opinion of the Investigator would interfere with the patient's participation in and/or completion of the study
3. Patient has history of endogenous allergic reactivity
4. The patient has a known immune deficiency from any disease, or a condition associated with an immune deficiency
5. The patient is receiving immunosuppressive or immunomodulating agents or cytotoxic therapy, or any medication that, in the opinion of the Investigator, might interfere with the study
6. Patients with severe renal failure at the screening visit (as defined by glomerular filtration rate less than 30 ml/min/1.73 m² by Cockcroft and Gault calculation), hyperlipidemia is allowed
7. The patient has liver disease such as cirrhosis or chronic active hepatitis

Exclusion criteria removed on 05/03/2007: severe ketonuria (+++ on urine stix testing; ++ on repeated urine stix testing)

Date of first enrolment

01/10/2005

Date of final enrolment

31/08/2010

Locations

Countries of recruitment

United Kingdom

Austria

Czech Republic

Finland

France

Germany

Greece

Israel

Italy

South Africa

Spain

Study participating centre
Universita' Campus Bio-Medico
Rome
Italy
00155

Sponsor information

Organisation
Andromeda Biotech Ltd (Israel)

ROR
<https://ror.org/00kyj9h67>

Funder(s)

Funder type
Industry

Funder Name
Andromeda Biotech Ltd (Israel)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014		Yes	No
Results article	results	01/07/2014		Yes	No
Basic results				No	No